

CHAPTER

8

**Improving Medicare's policies
for separately payable drugs
in the hospital outpatient
prospective payment system**

R E C O M M E N D A T I O N S

- 8-1** The Congress should direct the Secretary to modify the pass-through drug policy in the hospital outpatient prospective payment system so that it:
- includes only drugs and biologics that function as supplies to a service, and
 - applies only to drugs and biologics that are clinically superior to their packaged analogs.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1

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- 8-2** The Secretary should specify that the separately payable non-pass-through policy in the hospital outpatient prospective payment system applies only to drugs and biologics that are the reason for a visit and meet a defined cost threshold.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1

Improving Medicare’s policies for separately payable drugs in the hospital outpatient prospective payment system

Chapter summary

The unit of payment in the hospital outpatient prospective payment system (OPPS) is the primary service, which is a service that is the reason for which a patient makes a visit to a hospital outpatient department (HOPD). During an outpatient visit, providers typically furnish ancillary services and supplies with the primary service. Under the OPPS, the costs of these ancillary items are generally “packaged” into the payment rate of the related primary service and paid for as a unit. Packaged payments encourage efficiency because the combination of inputs used to treat a patient determines whether the provider experiences a financial gain or loss.

Although packaging ancillary items has the benefit of encouraging efficiency, not all ancillary items are packaged under the OPPS. If an ancillary item is costly relative to the payment rate of the related primary service and infrequently used with that service, providers might avoid using that ancillary item if it were packaged because of the risk of financial loss. Therefore, under the OPPS, ancillary items that are relatively high cost are typically not packaged. The separate payment for some ancillary items under the OPPS contrasts with the inpatient prospective payment system (IPPS), which packages nearly all ancillary items. The rationale for packaging fewer ancillary items under the OPPS relative to the IPPS is that the size and cost of the payment units are smaller in the OPPS than in the IPPS. The unit of

In this chapter

- Background
- When are drugs separately payable under the OPPS?
- Concerns about OPPS policies for separately payable drugs
- Improving OPPS policy for new drugs that are supplies to a service
- Improving OPPS policy for drugs that are the reason for a visit
- Recommendations

payment in the OPPS is the primary service, while the unit of payment in the IPPS is an entire inpatient stay.

Like services, drugs that are furnished during HOPD visits can be the reason for the visit or can be ancillary supplies to a primary service. Medicare pays separately for most drugs that are the reason for a visit under the current structure of the OPPS, whereas most drugs used as ancillary supplies to a primary service are packaged into the payment rate of the applicable service. However, some drugs that are ancillary supplies to a service, new to the drug market, and costly in relation to the applicable service would be substantially underpaid if they were packaged with a primary service when they first come to market because the data are not sufficient to accurately reflect the costs of the drugs in the payment rates for the applicable services.

Through statute and regulatory action, the OPPS has two policies that provide separate payment for drugs: the pass-through policy and the separately payable non-pass-through (SPNPT) policy. Although both policies provide separate payments for drugs, they serve somewhat different purposes. The pass-through policy is focused on drugs that are new to the market and have costs that are high in relation to the OPPS payment rates for the applicable services (the services with which they would be packaged). The intent of the pass-through policy is to provide temporary separate payments to ensure adequate reimbursement for these drugs while CMS collects the data needed to establish accurate packaged payments. In contrast, the SPNPT policy is intended to provide adequate payment for relatively high-cost drugs that are already established in the drug market, such that they have been on the market too long to be eligible for the pass-through policy.

The Commission is concerned that the criteria for drugs to be eligible for separate payment under the OPPS do not strike an appropriate balance between promoting access to high-cost innovative treatments and maintaining pressure on providers to be efficient. Specific concerns include the following:

- The pass-through policy does not include a requirement that a drug show clinical superiority over similar treatments to qualify. Without a clinical superiority requirement, Medicare could pay separately for a drug no more effective than a competing drug already in use, even when the cost of the existing drug is reflected in the OPPS payment rate for the applicable service. This situation results in Medicare making additional payments for a drug that is no more effective than less costly drugs.
- Both the pass-through and SPNPT policies include drugs that are the reason for a visit. It would be more efficient administratively to pay separately for drugs that are the reason for a visit through a single policy.

- The payment rates for drugs that are the reason for a visit can differ depending on whether the drug is paid separately under the pass-through policy (as these drugs are during their first few years on the market) or under the SPNPT policy (as these drugs are after they are no longer eligible for pass-through status). By statute, OPPS payment rates for pass-through drugs are set at average sales price (ASP) + 6 percent, while CMS has established a policy of setting the payment rates for SPNPT drugs obtained through the 340B Drug Pricing Program at ASP – 22.5 percent. Consequently, providers that obtain their OPPS drugs through the 340B program—which account for more than 50 percent of Medicare spending for separately payable drugs in the OPPS—have a financial incentive to use pass-through drugs rather than similar SPNPT drugs.

To improve Medicare’s payments for drugs provided under the OPPS, the Commission recommends that the Congress modify the pass-through policy so that it includes only drugs that are supplies to a service and requires drugs to be clinically superior to other therapeutically similar drugs to be eligible for pass-through status. In addition, we recommend that the Secretary modify the SPNPT policy so that it explicitly applies only to drugs that are the reason for a visit, including those that are new to the market. ■

Background

The unit of payment in the hospital outpatient prospective payment system (OPPS) is the primary service, which is a service that is the reason a patient makes a visit to a hospital outpatient department (HOPD) and typically constitutes most of the resources required during the visit. During an outpatient visit, providers typically furnish ancillary services and supplies with the primary service. Under the OPPS, the costs of these ancillary items are generally packaged into the payment rate of the related primary service, and the primary service and the ancillary items are paid for as a unit. This packaging of ancillary items contrasts with a fee schedule, under which Medicare makes separate payments for the primary service and for each ancillary item. Making a single payment for a primary service and related ancillary items encourages efficiency because the combination of inputs used to treat a patient determines whether the provider experiences a financial gain or loss.

Although packaging ancillary items has the benefit of encouraging efficiency, not all ancillary items are packaged under the OPPS. If an ancillary item is costly relative to the payment rate of the related primary service and infrequently used with that service, only a small share of the cost of the ancillary item would be reflected in the payment rate. If the item were packaged with the related primary service under these circumstances, providers might avoid using the ancillary item because of the risk of financial loss. Therefore, under the OPPS, ancillary items that are relatively high cost are typically not packaged with primary services for purposes of payment. The separate payment of some ancillary items under the OPPS contrasts with the inpatient prospective payment system (IPPS), which packages nearly all ancillary items. The rationale for allowing separate payment for more ancillary items under the OPPS than under the IPPS is that the size and cost of the payment units are smaller in the OPPS. The unit of payment in the OPPS is the primary service delivered during a visit to an HOPD, while the unit of payment in the IPPS is an entire inpatient stay.¹

As with ancillary items provided under the OPPS, there is no separate payment for many drugs. Instead, the costs of these drugs are packaged into the payment rates of the related primary services. These packaged drugs are ancillary to a service, are relatively low cost, and generally serve as supplies. Packaging drugs does not mean that

there is no reimbursement to the providers that use these drugs. Instead, the costs of the drugs are at least partially reflected in the payment rates for the related services.

But not all drugs provided under the OPPS are packaged with primary services. The OPPS pays for many drugs and biologics (which we refer to collectively as “drugs”) by means of payments separate from the services that utilize them. These separately payable drugs have become an increasingly important component of the OPPS. From 2011 to 2019, Medicare spending for separately payable drugs under the OPPS rose from \$5.1 billion to \$14.8 billion. Most of this spending—73 percent in 2019—was for drugs used in cancer treatment.

In general, Medicare makes separate payments for OPPS drugs in two circumstances. First, separate payments are made for high-cost drugs that are the reason for a visit rather than being ancillary to a service (such as many chemotherapy drugs). Second, separate payments are made for some ancillary drugs (drugs that serve as supplies to a service) that have relatively high costs and those costs are not accurately reflected in the payment rate for the applicable primary service. This discrepancy occurs when a drug is new to the market and CMS does not have the cost and use data needed to appropriately incorporate the cost of the drug into the payment rate for the applicable service.

In our June 2020 report to the Congress, the Commission asserted that separate payments for drugs under the OPPS are appropriate in the following circumstances (Medicare Payment Advisory Commission 2020):²

- ***New drugs that are supplies to a service, are high cost, have a small share of their cost reflected in the applicable services, and show clinical superiority over similar drugs.*** CMS does not have the data needed to include in the payment rates for the applicable services the costs of new drugs that are supplies to a service. However, any new drug that is a supply to a service should be packaged if it does not show clinical superiority over existing similar drugs that are already packaged. Without a clinical superiority requirement, Medicare could pay separately for a new drug that is no more effective than a competing product already in use, even when the cost of the competing product is reflected in the OPPS payment for the related primary service. For a new high-cost ancillary drug that is clinically superior, separate payment should be time-limited; the drug

should be packaged once CMS has collected the necessary cost data.

- ***New and existing drugs that are the reason for a visit and have costs that exceed a threshold.*** A practical definition for these drugs is that they typically do not have any services provided during the visit other than the drug administration service. In these cases, the drug is, essentially, the primary service and the drug administration is ancillary. Many of these drugs are for cancer treatment, but some—such as infliximab, which treats autoimmune disorders—treat other conditions. However, if a drug that is the reason for a visit has relatively low costs, it is reasonable to package the costs of the drug into the payment rate for the applicable drug administration service. Therefore, a policy for separate payment of drugs that are the reason for a visit should require a drug to have costs per day that exceed a specified threshold.

The Commission is concerned that the OPPS policies for separately payable drugs do not strike an appropriate balance between promoting access to high-cost innovative treatments and maintaining pressure on providers to be efficient. In this chapter, we review Medicare’s policies for separately payable drugs under the OPPS and provide recommendations for improvement.

When are drugs separately payable under the OPPS?

Through statute and regulatory action, the OPPS has two policies that provide separate payment for drugs: the pass-through policy and the separately payable non-pass-through (SPNPT) policy. Although both policies provide separate payments for drugs, they serve somewhat different purposes. The pass-through policy provides temporary separate payments for relatively high-cost drugs that are new to the market. The purpose is to provide adequate payment for these drugs because the data needed to include their costs in the payment rates of the applicable services are not available, simply because the drugs are new. When the needed data become available, CMS can include the costs of these drugs in the payment rates of the applicable services. In contrast, the SPNPT policy is intended to provide adequate payment for relatively high-cost drugs that are already established in the drug market—meaning the drug has been on the market too

long to be eligible for the pass-through policy. CMS has always required that a drug’s cost per day must exceed a threshold to have SPNPT status.

Drugs that do not have either pass-through status or SPNPT status are packaged under the OPPS. These drugs include new products that do not meet the criteria for obtaining pass-through status and established drugs that either do not meet the criteria for the SPNPT policy or are “policy-packaged” drugs, which include anesthesia drugs; drugs, biologics, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologics that function as supplies when used in a surgical procedure. The definition of policy-packaged drugs includes virtually all non-pass-through drugs except those that are the reason for a visit, such as chemotherapy drugs. Therefore, only drugs that are the reason for a visit can be SPNPT drugs.

Pass-through drugs

As policymakers were developing the OPPS, there was concern that data on the cost of new drugs would not be available when setting the payment rates for services in the OPPS. Without the necessary cost data, packaging these drugs with the applicable primary services could result in providers being underpaid for the new drugs because the costs would not be accurately reflected in the payment rates for the services. As a result, providers might avoid using the new drugs. The Congress addressed this issue in Section 1833(t)(6) of the Social Security Act by establishing pass-through payments for new drugs that have high costs relative to the payment rates of their associated primary services. Under this policy, when a provider uses a pass-through drug, CMS pays the provider for the primary service (and any packaged services and supplies associated with the service), plus an additional payment to reflect the estimated cost of the pass-through drug (minus the value of any therapeutically similar established drug that is already packaged with the primary service).

The requirements for a drug to be granted pass-through status include the following (Centers for Medicare & Medicaid Services 2014):

- It must be new to the market, meaning that payment for the product was not made as of December 31, 1996.³

- The cost of the product is “not insignificant” in relation to the OPPS payment rate for the related service. CMS has determined that drug costs are not insignificant if they meet these three thresholds (see text box, pp. 284–285, for hypothetical examples):
 - The estimated average reasonable cost of the drug or biologic must exceed 10 percent of the applicable ambulatory payment classification (APC) payment amount for the service related to the drug or biologic.⁴
 - The estimated average reasonable cost of the drug or biologic must exceed the drug or biologic portion of the APC payment amount for the related service by at least 25 percent.
 - The difference between the estimated reasonable cost of the drug or biologic and the estimated portion of the APC payment amount for the drug or biologic must exceed 10 percent of the APC payment amount for the related service.

Drugs that meet both the “new” criterion and the three cost thresholds are granted pass-through status, but these drugs are not required to demonstrate clinical superiority over established drugs. Drugs can hold pass-through status for two to three years. By the time a drug’s pass-through status has expired, CMS has adequate cost and use data about the drug to package the cost of the drug with the payment rate for the applicable primary service. However, most pass-through drugs are not packaged with primary services after expiration of pass-through status but rather continue to be separately paid under the SPNPT policy.

The formal definition of a pass-through payment is “the amount determined under Section 1842(o) of the Social Security Act minus the portion of the APC payment amount that CMS determines is associated with the drug or biologic” (Centers for Medicare & Medicaid Services 2019b). The amount determined under Section 1842(o) is the drug’s average sales price plus 6 percent (ASP + 6 percent). Therefore, a pass-through payment should be the difference between ASP + 6 percent for the pass-through drug and the cost of similar drugs (if any) reflected in the OPPS payment rate for the applicable primary service.

In practice, CMS uses a system in which pass-through payment eligibility depends on whether a drug is a supply to a service or the reason for the visit (Figure 8-1, p. 286). For pass-through drugs that are supplies to a service, CMS

calculates the pass-through payment as the difference between ASP + 6 percent for the pass-through drug and an “offset” that equals the amount of the cost of any drug that is clinically similar to the pass-through drug that is reflected in the payment rate for the applicable service. The difference between ASP + 6 percent and the offset amount is the payment amount the provider receives for the pass-through drug. For drugs that are the reason for a visit, CMS calculates the pass-through amount simply as ASP + 6 percent, with no offset. (See text box, p. 287, on calculating pass-through payments for illustrative examples.)

Separately payable non-pass-through drugs

The SPNPT policy focuses on higher cost drugs that have been on the market long enough for CMS to have collected the data needed to include their costs in the payment rates of the applicable services. To qualify for SPNPT status, a drug:

- must not be a pass-through drug,
- must have a cost per day that exceeds a threshold (\$130 in 2021) that is adjusted each year for drug inflation, and
- cannot be a policy-packaged drug (that is, the drug cannot be a supply to a service).

The fact that SPNPT drugs cannot be policy-packaged drugs indicates that SPNPT drugs are the reason for a visit.

The SPNPT policy is distinct from the pass-through policy in four important ways (Table 8-2, p. 288). First, the SPNPT policy is for established drugs, while the pass-through policy is for new drugs. Second, the SPNPT policy has no limit on how long a drug can hold SPNPT status, while the pass-through policy limits eligibility to two to three years. Third, SPNPT drugs must exceed a single cost per day threshold, while pass-through drug costs must exceed three thresholds related to the payment rate of the associated service. Fourth, payment rates for pass-through drugs, set in statute, must be based on ASP + 6 percent, while payment rates for SPNPT drugs have been set by CMS through regulation at ASP – 22.5 percent if the drug is obtained through the 340B Drug Pricing Program and ASP + 6 percent if the drug is not obtained through the 340B program.⁵ Neither policy requires drugs to show clinical superiority over other drugs.

Determining pass-through status for drugs under current OPSS policy: Illustrative examples

The hospital outpatient prospective payment system (OPSS) has a pass-through payment policy for drugs that are new to the market. To qualify for pass-through payments, a new drug must meet all three cost criteria:

- The estimated average reasonable cost of the drug or biologic must exceed 10 percent of the applicable ambulatory payment classification (APC) payment amount for the service related to the drug or biologic.
- The estimated average reasonable cost of the drug or biologic must exceed the drug or biologic portion of the APC payment amount for the related service by at least 25 percent.
- The difference between the estimated reasonable cost of the drug or biologic and the estimated portion of the APC payment amount for the drug or biologic must exceed 10 percent of the APC payment amount for the related service.

Two hypothetical examples illustrate how CMS determines whether a drug meets these three cost criteria. In one example, a drug meets the three criteria; in the other example, the drug does not meet any of the criteria.

Example 1: New drug meets the three cost criteria for pass-through drugs

A new drug has a cost of \$100 per dose and is used with a service that has an OPSS payment rate of \$500. This OPSS payment rate includes \$40 for the cost of an established drug that has a therapeutic use similar to the new drug's. To determine whether the new drug meets the pass-through cost criteria under current policy, CMS would address these three questions:

- ***Does the cost of the new drug exceed 10 percent of the APC payment rate for the applicable service?*** The cost of the new drug (\$100) divided by the payment rate for the applicable service (\$500) is 0.2, which means the cost of the drug is 20 percent of the OPSS payment rate of the applicable service. Therefore, this drug meets this cost criterion.
- ***Is the cost of the new drug more than 25 percent higher than the drug costs reflected in the APC payment rate for the applicable service?*** The cost of the new drug (\$100) is 150 percent higher than the cost of the established drug that is reflected in the APC payment rate of the applicable service (\$40). Therefore, this drug meets this cost criterion.

(continued next page)

The OPSS packages drugs that do not have pass-through status or SPNPT status. These drugs include new products that do not have pass-through status and established drugs that either cost less than \$130 per day or are policy-packaged drugs. Under no circumstances are policy-packaged drugs paid separately under the SPNPT policy.

Concerns about OPSS policies for separately payable drugs

The Commission is concerned that the criteria for eligibility for separate payment under the OPSS do not strike an appropriate balance between promoting access to high-cost innovative treatments and maintaining pressure on providers to be efficient. One concern is that the pass-

Determining pass-through status for drugs under current OPSS policy: Illustrative examples (cont.)

- ***Does the difference between the cost of the new drug and the drug costs that are reflected in the APC payment rate for the applicable service exceed 10 percent of the APC payment rate for the applicable service?*** The difference between the cost of the new drug (\$100) and the cost of the established drug that is reflected in the applicable APC payment rate (\$40) is \$60, which is 12 percent of the OPSS payment rate of the applicable service (\$500). Therefore, this drug meets this cost criterion.

CMS would not consider the new drug's efficacy relative to established packaged drugs in determining eligibility for pass-through payments. Because the new drug meets all three pass-through cost criteria, it would be granted pass-through status.

Example 2: New drug does not meet any of the three cost criteria for pass-through drugs

A new drug has a cost of \$80 per dose and is used in a service that has an APC payment rate of \$1,000. The APC payment rate includes \$70 for the cost of an established drug that has a therapeutic use similar to the new drug's. To determine whether the new drug meets the pass-through cost criteria, CMS would ask the same three questions:

- ***Does the cost of the new drug exceed 10 percent of the APC payment rate for the applicable service?*** The cost of the new drug (\$80) divided by the payment rate for the applicable service (\$1,000)

is 0.08, or 8 percent of the APC payment rate of the applicable service. Therefore, this drug does not meet this cost criterion.

- ***Is the cost of the new drug more than 25 percent higher than the drug costs that are reflected in the OPSS payment rate of the applicable service?*** The cost of the new drug (\$80) is 14.3 percent higher than the cost of the established drug that is reflected in the APC payment rate for the applicable service (\$70). Therefore, this drug does not meet this cost criterion.
- ***Does the difference between the cost of the new drug and the drug costs that are reflected in APC payment rate for the applicable service exceed 10 percent of the APC payment rate for the applicable service?*** The difference between the cost of the new drug (\$80) and the cost of the established drug that is reflected in the applicable APC payment rate (\$70) is \$10, which is 1 percent of the APC payment rate of the applicable service (\$1,000). Therefore, this drug does not meet this cost criterion.

CMS would not consider the new drug's efficacy relative to existing packaged drugs in making the decision of eligibility for pass-through payments. Because the drug meets none of the cost criteria, it would not qualify for a separate payment under the pass-through policy and instead would be packaged with the applicable primary service. ■

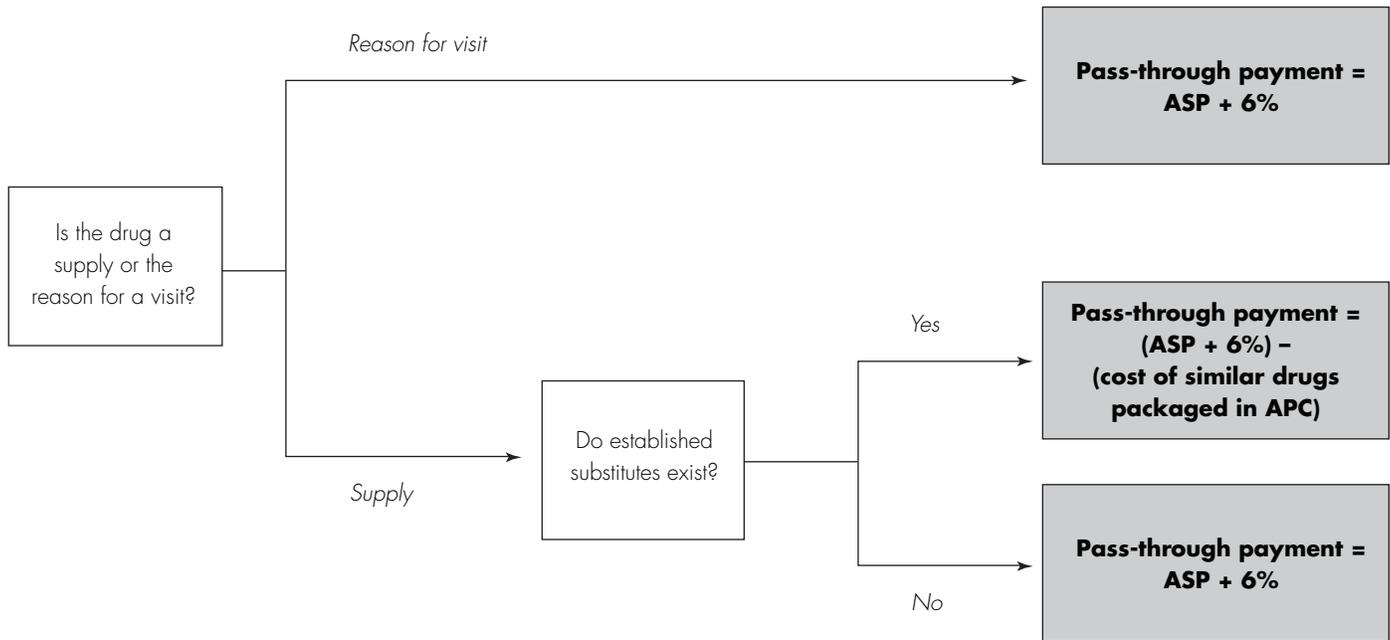
through policy does not include a requirement that a new drug show clinical superiority over established drugs that have similar clinical uses. Without a clinical superiority requirement, when a hospital uses a pass-through product, it is possible that Medicare will make additional payments for a drug that has no clinical benefit over similar drugs

that are included in the payment rate for the applicable service.

Another concern is that both the pass-through and SPNPT policies include drugs that are the reason for a visit. This overlap of the two policies causes the relatively minor issue that the OPSS system of drug payment is more

FIGURE 8-1

Determining payment for OPPTS pass-through drugs under current policy



Note: OPPTS (outpatient prospective payment system), ASP (average sales price), APC (ambulatory payment classification).

Source: MedPAC analysis.

complex than necessary. It would be more administratively efficient to pay separately for drugs that are the reason for a visit through a single policy.

A more substantive issue related to the overlap of the pass-through and SPNPT policies is that for providers obtaining drugs through the 340B Drug Pricing Program, it can be financially beneficial to choose a pass-through drug over a similar SPNPT drug. By statute, pass-through drugs must be paid at a rate of ASP + 6 percent, while CMS has established a policy that sets the payment rates for SPNPT drugs obtained through the 340B program at ASP – 22.5 percent. (CMS sets the payment rates for SPNPT drugs obtained outside the 340B program at ASP + 6 percent.) Therefore, providers participating in the 340B program face different payment policies for pass-through and SPNPT drugs, with the pass-through drugs having the pricing advantage. Because of these pricing differences, some pass-through drugs are more profitable than similar SPNPT drugs, making the pass-through drugs

more financially attractive. Because more than 50 percent of the OPPTS spending for separately payable drugs occurs at 340B hospitals, this difference in pricing between pass-through and SPNPT drugs is important.⁶

Improving OPPTS policy for new drugs that are supplies to a service

Medicare’s OPPTS payment policy for new drugs that are supplies to a service would be improved by focusing the pass-through policy on these drugs and requiring them to show clinical superiority over other drugs that have similar clinical uses as a condition of receiving separate payments. About 15 percent of the drugs that are separately payable under the current OPPTS pass-through policy are drugs that are supplies to a service; the remaining 85 percent are drugs that are the reason for a visit. Restricting the pass-through policy to those drugs that function as supplies

Calculating pass-through payments for drugs under current OPPS policy: Illustrative examples

CMS uses two methods to calculate pass-through payments for drugs in the outpatient prospective payment system (OPPS). One method is for drugs that are supplies to a service, the other is for drugs that are the reason for a visit. We provide examples of how pass-through payments are calculated for both drug categories under current policy.

For pass-through drugs that are supplies to a service, we use Puraply as an example. Puraply is a skin substitute that had pass-through status through the end of 2020 (it is now packaged). The OPPS covers many skin substitutes, and all of them are packaged unless they have pass-through status. The service that most frequently uses Puraply is represented by Current Procedural Terminology (CPT) code 15271 (application of skin substitute graft to trunk, arms, or legs). The OPPS payment rate for Puraply in 2020 was \$105 per square centimeter, and the payment rate for CPT 15271 was \$1,623. Using claims data, we estimated that the mean amount of Puraply used with CPT 15271 was 11 square centimeters. The pass-through payment when a provider used the mean number of units of Puraply in 2020 was the base payment amount of \$1,155 ((11

square centimeters) × (\$105 per square centimeter)) minus the cost of the other skin substitutes packaged into the payment rate of CPT 15271 (\$760), which resulted in a pass-through payment of \$395 (\$1,155 minus \$760) (Table 8-1). In addition to the payment for CPT 15271, the provider would have received a pass-through payment of \$395 for the provision of Puraply.

For pass-through drugs that are the reason for a visit, we use Bendeka as an example. Bendeka is an alkylating agent used to treat chronic lymphocytic leukemia. In 2021, the OPPS payment rate for Bendeka was \$20.27 per milligram. Because this drug is the reason for a visit, the pass-through payment in 2020 was the full payment rate of \$20.27 times the number of units used by the provider, with no offset. This amount is also the payment received by the provider. The pass-through payment for Bendeka contrasts with the pass-through payment for Puraply: The payment for Bendeka is simply the full OPPS payment rate, while the payment for Puraply is the full OPPS payment rate less the cost of the other skin substitutes in the payment rate for CPT code 15271. ■

**TABLE
8-1**

Pass-through payment amount for Puraply skin substitute, 2020

	Amount
Total payment amount for 11 square centimeters* of Puraply	\$1,155
Cost of established skin substitutes in payment rate for applicable skin procedure	<u>– \$760</u>
Pass-through payment for Puraply	\$395

Note: The applicable skin procedure for Puraply is “application of skin substitute graft to trunk, arms, or legs.”

*The mean number of units of Puraply used by providers covered under the outpatient prospective payment system is 11 square centimeters.

Source: MedPAC analysis of payment rates in the outpatient prospective payment system (OPPS) and data on the cost of drugs packaged into the payment rates of services covered under the OPPS, 2020. Both data sources are from CMS.

would exclude drugs that are the reason for a visit. (New drugs that are the reason for a visit would be eligible for separate payments only under the SPNPT policy, as discussed below.) During the period of a drug’s pass-through eligibility, CMS would collect the data needed to incorporate the cost of the pass-through drug into the

payment rate of the applicable service (as the agency currently does) once the drug’s pass-through eligibility expired.

The Commission has asserted that clinical superiority should be a requirement for a new drug to be granted

**TABLE
8-2**

Current OPSS policies for pass-through drugs and separately payable non-pass-through drugs have important differences, but neither requires clinical superiority

Program feature	Pass-through drugs	Separately payable non-pass-through drugs
Required to be new to market	Yes	No
Time limit	Two to three years	No
Cost requirement	Cost must exceed three thresholds related to associated service	Cost must exceed \$130 per day
Payment rate	ASP + 6 percent	ASP – 22.5% if obtained through 340B program ASP + 6% if obtained outside 340B program
Clinical superiority requirement	No	No

Note: OPSS (outpatient prospective payment system), ASP (average sales price).

Source: Final rule regulations on the hospital outpatient prospective payment system for calendar year 2021 from CMS.

separately payable status. Applying this principle to the pass-through policy means that it should be modified so it includes the current criteria but also includes a clinical superiority requirement as a condition for pass-through eligibility (Medicare Payment Advisory Commission 2020). The benefits of adding a clinical superiority requirement to the pass-through policy include the following:

- Medicare would make additional pass-through payments only if a new drug is clinically superior to established drugs that have similar therapeutic uses. New drugs that are not clinically superior would be packaged with the applicable service and paid at the established rate for the packaged service and clinically similar drugs.
- Manufacturers would have to meet a meaningful criterion to have a drug eligible for pass-through payments, beyond simply meeting the pass-through cost criteria. Therefore, manufacturers would have an incentive to dedicate more resources to developing drugs that offer better clinical outcomes and fewer resources to new products that are profitable but offer little in terms of better clinical outcomes.

We also assert that CMS should not grant pass-through status or make pass-through payments until a drug has clearly established that it is clinically superior to competing drugs. Such an approach would be consistent

with the Commission’s effort to provide greater value in all Medicare fee-for-service (FFS) payment systems over the last decade.

Clinical superiority requirements for new technologies are included in several Medicare FFS payment systems, including for new equipment and supplies in the end-stage renal disease prospective payment system (PPS), new devices in the OPSS, and new drugs and devices in the new technology add-on payment (NTAP) program in the IPPS. A clinical superiority requirement for new drugs to be eligible for the OPSS’s pass-through payment could be beneficial beyond the OPSS because it could encourage greater use of clinical superiority requirements for new technology in other FFS payment systems.

A clinical superiority requirement in the pass-through policy would compare the performance of a new drug with established drugs that have similar clinical uses. If the new drug were clinically better in some way, such as resulting in faster resolution of the disease process, then the drug would be eligible for pass-through status. Although several FFS Medicare payment systems have clinical improvement requirements for new technology, only the NTAP program in the IPPS includes pharmaceutical products. Therefore, the NTAP program could serve as a guide for establishing a clinical superiority requirement for pass-through drugs in the OPSS (see text box on clinical superiority criteria).

Clinical superiority criteria for drugs eligible for new technology add-on payments under Medicare's inpatient prospective payment system

Medicare's new technology add-on payment (NTAP) program under the inpatient prospective payment system applies to new drugs and technologies. Under the NTAP program, a drug demonstrates clinical superiority if it meets any one of the following criteria (Centers for Medicare & Medicaid Services 2019a):

- The drug offers a treatment option for a patient population unresponsive to, or ineligible for, other available treatments.
- The drug offers the ability to diagnose a medical condition in a patient population for which that medical condition is otherwise undetectable or offers the ability to diagnose a medical condition earlier in a patient population than possible through other methods, and use of the drug affects the management of the patient.
- Use of the drug improves clinical outcomes relative to other drugs, such as:
 - a reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication;
- a decreased rate of at least one subsequent diagnostic or therapeutic intervention (for example, due to reduced rate of recurrence of the disease process);
- a decreased number of future hospitalizations or physician visits;
- a more rapid beneficial resolution of the disease process including, but not limited to, a reduced length of stay or recovery time, an improvement in one or more activities of daily living, an improved quality of life, or a demonstrated greater medication adherence or compliance.
- The totality of the circumstances otherwise demonstrates that the drug substantially improves, relative to other drugs, the diagnosis or treatment of Medicare beneficiaries. ■

Improving OPSS policy for drugs that are the reason for a visit

The current SPNPT policy is implicitly restricted to established drugs that are the reason for a visit. To improve OPSS payment for drugs that are the reason for a visit, the SPNPT policy should be expanded to include all such drugs, both new and established. Expanding the SPNPT policy would result in new drugs that are the reason for a visit immediately becoming eligible for SPNPT payments, rather than initially receiving payments under the pass-through policy.

Expanding the SPNPT policy to include new drugs that are the reason for a visit would also mitigate the effects of

the OPSS pricing differences between the pass-through and SPNPT policies that create an incentive for 340B providers to use pass-through drugs rather than clinically similar SPNPT drugs.

To ensure the clarity of the purpose of the SPNPT policy and to reduce the incentive for providers to choose drugs based on financial considerations, the SPNPT policy should be redefined such that:

- only drugs that are the reason for the visit would be separately paid under the SPNPT policy.⁷
- it includes drugs that are new to the market as well as drugs that are already established on the market.

Recommendations

Implementing the changes that we have outlined for the system of drug payment in the OPSS would leave both the pass-through and SPNPT policies intact, but with important modifications (Figure 8-2). To qualify for pass-through payments, drugs would have to:

- be supplies to a service (ancillary), meaning that the drug could not be the reason for a visit.
- be new to the market, meaning that the drug had not been on the market long enough for CMS to have the data necessary to package the cost of the drug with the payment rate of the applicable service.
- meet the current three criteria for cost being “not insignificant” in relation to the payment rate for the service associated with the drug.
- show clinical superiority over similar drugs used in provision of the same service.

Drugs that are supplies to a service and that do not have pass-through status would continue to be packaged with their associated services.

To qualify for SPNPT payments, both new and established drugs would have to:

- be the reason for the visit and
- have a cost per day that exceeds a dollar threshold. The current threshold is \$130 per day (and annually adjusted for inflation), but CMS should reevaluate to determine whether \$130 per day is the appropriate level.

RECOMMENDATION 8 - 1

The Congress should direct the Secretary to modify the pass-through drug policy in the hospital outpatient prospective payment system so that it:

- **includes only drugs and biologics that function as supplies to a service, and**
- **applies only to drugs and biologics that are clinically superior to their packaged analogs.**

RECOMMENDATION 8 - 2

The Secretary should specify that the separately payable non-pass-through policy in the hospital outpatient prospective payment system applies only to drugs and biologics that are the reason for a visit and meet a defined cost threshold.

RATIONALE 8 - 1 AND 8 - 2

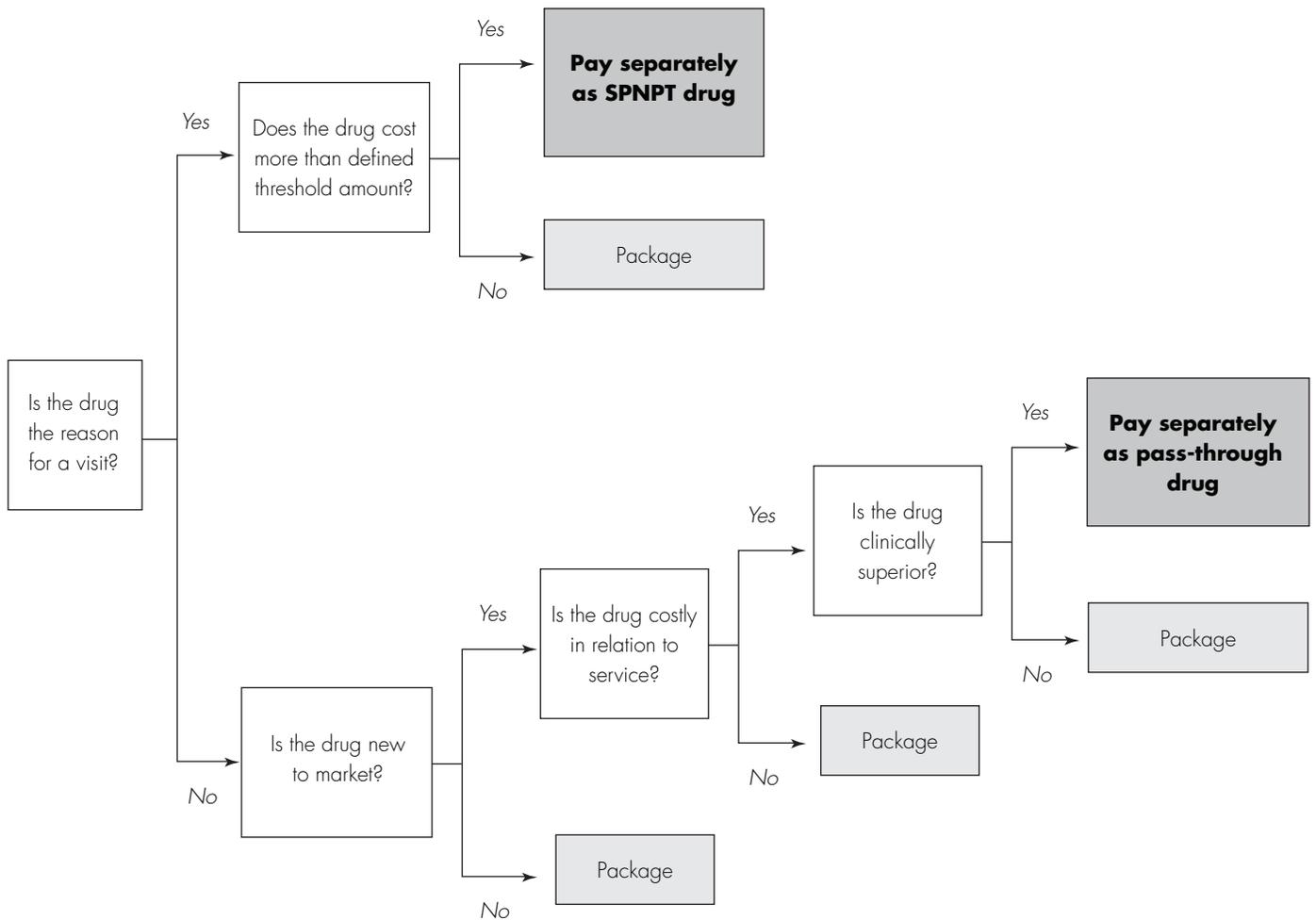
The important effects of these recommendations include the following:

- The clinical superiority requirement in the pass-through policy would raise the bar for drugs to qualify for separate payments under the OPSS beyond simply meeting the pass-through cost criteria. Drug manufacturers would have an incentive to devote resources to developing drugs that offer better clinical performance than existing drugs.
- Drugs that are the reason for a visit would be excluded from the pass-through policy, and most of them would be separately payable under the SPNPT policy (if they exceeded the cost per day threshold). This change in payment status for new drugs that are the reason for a visit would mitigate the effects of the OPSS pricing difference between pass-through drugs and SPNPT drugs.
- Each year, the number of pass-through drugs would be substantially lower than the number that currently qualify for pass-through status because pass-through status would exclude drugs that are the reason for a visit and would require clinical superiority over similar drugs.
- In the first year of implementing the proposed policy, the number of SPNPT drugs would increase because many pass-through drugs that are the reason for a visit would be moved to the SPNPT category.
- The number of packaged drugs would increase. The requirement that new products that function as a supply must show clinical superiority to be given pass-through status would decrease the number of pass-through drugs.

Though this shift of drugs from pass-through status to either SPNPT status or packaged status would change the OPSS payment rates for these drugs, initially there would be no effect on Medicare spending. Most drugs no longer eligible for pass-through status would be eligible for SPNPT status instead. OPSS payments for these drugs would change from ASP + 6 percent under the pass-through policy to either ASP + 6 percent or ASP – 22.5 percent, depending on whether the drug is obtained through the 340B program. This change in payment rates would affect OPSS drug spending, but any decrease in OPSS drug spending would trigger a proportional increase in the payment rates of other OPSS services to maintain

FIGURE 8-2

Decision criteria under the Commission’s recommended changes to separately payable drug policies in the OPSS



Note: OPSS (outpatient prospective payment system), SPNPT (separately payable non-pass-through).

Source: MedPAC analysis.

statutorily mandated budget neutrality. The movement of some pass-through drugs to packaged status because they do not meet the clinical superiority requirement also would have no effect on Medicare spending because of the budget-neutrality requirement.

Over the longer term, however, Medicare spending would likely be affected. Providers would likely change their drug choices as drug payment rates changed, generally from pass-through drugs that currently have payment rates

set at ASP + 6 percent to SPNPT drugs that have payment rates set at ASP – 22.5 percent. These changes in drug choices would reduce Medicare program spending. In addition, adding a clinical superiority requirement to the pass-through policy would likely mitigate the inflationary pressure on drug prices. A clinical superiority requirement would give drug manufacturers greater incentive to develop more efficacious drugs, and less incentive to develop drugs that can qualify for the pass-through policy simply based on cost.

Although the recommendations would result in an improved system of drug payment in the OPSS, an important issue not addressed is setting payment rates for biosimilars. The policy for setting payment rates for a brand-name drug and its generic competitors differs from the policy for setting payment rates for a reference biologic and its biosimilar competitors. The generic drug policy has helped slow the rate of Medicare spending on drugs. Under that policy, a new generic drug and its related brand-name drug are assigned to the same billing code—a consolidated billing code—and have the same payment rate. Because of the single billing code and the low research and development costs for generic drugs, Medicare payment rates for drugs that become generic generally decline substantially over time (Medicare Payment Advisory Commission 2010). In contrast, under current policy, a new biosimilar is assigned a billing code that is separate from the billing code for the reference biologic, which does not maximize price competition between the reference biologic and the biosimilar because the payment rates for the biosimilar and the reference biologic are based on their respective ASPs.

The current policy of assigning the biosimilar and its reference biologic to different billing codes conflicts with the Commission's fundamental payment principle that Medicare should pay similar rates for similar care. The Commission has addressed this issue by recommending that the Congress require the Secretary to use a common billing code to pay for a reference biologic and its biosimilars (Medicare Payment Advisory Commission 2017). A key issue for implementing a common billing code for a reference biologic and its biosimilars is how CMS would set a single payment rate for the billing code. The Commission suggested CMS could base the payment rate according to the volume-weighted ASP of the products assigned to the code. CMS currently uses such an approach when determining the payment rate for a brand drug and its associated generic drugs. However, other options could be used, such as basing payment on the lowest ASP among the products in the same billing code.

Spending

- The Congressional Budget Office (CBO) estimates these recommendations will have no effect on Medicare spending over a one-year or five-year period. CBO's estimate reflects a mandated budget-neutrality requirement in the OPSS. Under the recommendations, we expect Medicare spending on drugs covered under the OPSS would decline. However, under statute, CMS would be required to adjust the OPSS payment rates for all services to fully offset any change in spending for drugs.
- Although difficult to quantify, Medicare spending would decline to the extent that these recommendations affect providers' choice of drugs furnished to beneficiaries. These recommendations would mitigate current financial incentives for 340B providers to choose pass-through drugs over clinically similar SPNPT drugs because current policies tend to produce higher payment rates for pass-through drugs relative to SPNPT drugs. These changes in drug choices would not be accounted for in CMS's budget-neutrality adjustments to the OPSS but rather would reduce Medicare program spending. In addition, we expect that adding a clinical superiority requirement to the pass-through policy would likely reduce the inflationary pressure on drug prices in the long term.

Beneficiary and provider

- We do not expect these recommendations to have adverse effects on beneficiaries' access to drugs needed for effective treatment. Mitigating financial incentives for 340B providers to choose certain drugs may affect choices within categories of similar drugs. We do not expect the recommendations to affect providers' willingness or ability to care for Medicare beneficiaries. ■

Endnotes

- 1 Under the IPPS, there is some opportunity for hospitals to unbundle some ancillary items. For example, if an expensive drug is provided in an outpatient department to an inpatient on the day of discharge, the drug is paid separately from the inpatient stay.
- 2 Although separate payment for some drugs is reasonable under the current structure of the OPSS, future policies that would encourage more price competition among drugs, such as reference pricing or consolidated billing, are not precluded by this discussion. It is not inconsistent with the current structure of the OPSS to classify drugs into the larger payment categories required by reference pricing or consolidated billing. Indeed, doing so would make drug payment more consistent with OPSS payment for services, under which services are classified into somewhat broad payment categories (ambulatory payment classifications).
- 3 The Congress defined new drugs as those for which payment was not made as of December 31, 1996, because payment rates for the initial OPSS were based on data from 1996. In a practical sense, this requirement means drugs are considered new if no payment is made during the period for which CMS is using data to determine OPSS payment rates. For example, CMS used data from 2019 to determine OPSS payment rates for 2021. If a drug was introduced to the market in 2020, it would be considered new to the market.
- 4 APCs are the OPSS analog to diagnosis related groups used in the inpatient prospective payment system. CMS classifies services into APCs based on clinical and cost similarity. That is, CMS attempts to create APCs that have services that have similar costs and similar clinical purposes. All services in the same APC have the same OPSS payment rate.
- 5 For five years (2013 through 2017), CMS set OPSS payment rates for SPNPT drugs at ASP + 6 percent, irrespective of whether they were obtained through the 340B program.
- 6 The 6 percent add-on to ASP has received attention because of concern that it may create incentives for use of higher priced drugs when lower priced alternatives exist. Since 6 percent of a higher priced drug generates more revenue for providers than 6 percent of a lower priced drug, selection of the higher priced drug may generate more profit, depending on the provider's acquisition cost for the two drugs. Policymakers could use a number of approaches to address potential adverse incentives associated with the 6 percent add-on, including a lower percentage add-on (as the Commission recommended in 2017) or replacing the 6 percent add on with a flat dollar add-on or a combination of a flat dollar add-on and a lower percentage add-on (Medicare Payment Advisory Commission 2017, Medicare Payment Advisory Commission 2016, Medicare Payment Advisory Commission 2015).
- 7 Policymakers could separately reassess the level of the cost threshold in conjunction with the revised SPNPT policy.

References

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2019a. Application for new medical technologies and technologies seeking to qualify for add-on payments under the hospital inpatient prospective payment system for the federal fiscal year (FY) 2021. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech>.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2019b. Medicare program: Changes to hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs; revisions of organ procurement organizations conditions of coverage; prior authorization process and requirements for certain covered outpatient department services; potential changes to the laboratory date of service policy; changes to grandfathered children's hospitals-within-hospitals; notice of closure of two teaching hospitals and opportunity to apply for available slots. Final rule. *Federal Register* 84, no. 218 (November 12): 61142–61492.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014. Process and information required to determine eligibility of drugs, biologicals, and radiopharmaceuticals for transitional pass-through status under the hospital outpatient prospective payment system (OPPS). <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/drugapplication.pdf>.

Medicare Payment Advisory Commission. 2020. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2015. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2010. *Report to the Congress: Aligning incentives in Medicare*. Washington, DC: MedPAC.